

Notice of Allowability

Application No.

09/341,829

Examiner

MINH-TAM DAVIS

Applicant(s)

LETHE ET AL.

Art Unit

1642

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to interviews of 02/10, 18, 19/04 and 03/01/04.
2. ☒ The allowed claim(s) is/are 1-3, 7, 17-19, 38, 58-59, renumbered as 1-10.
3. ☐ The drawings filed on _____ are accepted by the Examiner.
4. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) ☐ All b) ☐ Some* c) ☐ None of the:
 1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

* Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.

THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

5. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
 6. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
 - (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
 - 1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
 - (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
7. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

1. ☐ Notice of References Cited (PTO-892)
2. ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3. ☒ Information Disclosure Statements (PTO-1449 or PTO/SB/08),
Paper No./Mail Date 01/23/04, 02/19/04, 02/23/04
4. ☐ Examiner's Comment Regarding Requirement for Deposit
of Biological Material
5. ☐ Notice of Informal Patent Application (PTO-152)
6. ☒ Interview Summary (PTO-413),
Paper No./Mail Date 03/01/04
7. ☒ Examiner's Amendment/Comment
8. ☐ Examiner's Statement of Reasons for Allowance
9. ☐ Other _____.

EXAMINER'S AMENDMENT

1. An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with John van Amsterdam on 02/26/03 and 03/01/04.

The application has been amended as follows:

In the specification:

The continuation data has been inserted on the first line of the specification as follows:

This application is a US national stage Application of PCT/US 98/01445, filed 01/27/1998, which is a continuation-in-part of US Application serial number 08/791,495, now abandoned.

In the claim:

Claim 7 has been amended as follows:

Claim ⁴7. (Currently amended) An isolated nucleic acid molecule selected from the group consisting of:

(a) a fragment of nucleotides 1-993 of SEQ ID NO:4 consisting of contiguous nucleotides between 15 and 922 in length, said fragments found only in SEQ ID NO:4, and

(b) full length complete complement of "(a)".

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Claim 38 has been amended as follows:

Claim ~~38~~⁸. (Currently amended) A method for diagnosing cancer, comprising:
contacting a biological sample isolated from a subject with a probe that hybridizes under high stringency hybridization conditions to SEQ ID NO:4, wherein the probe consists of the isolated nucleic acid molecule of claim 1a or claim 1c, wherein the high stringency hybridization conditions are hybridization at 65°C in hybridization buffer (3.5 x SSC, 0.02% Ficoll, 0.02% polyvinyl pyrrolidone, 0.02% Bovine Serum Albumin, 25 mM NaH₂PO₄ (pH 7), 0.5% SDS, 2 mM EDTA), wherein SSC is 0.15 M sodium chloride/0.015 M sodium citrate, pH 7; SDS is sodium dodecyl sulphate; and EDTA is ethylenediaminetetracetic acid and washing at 2 x SSC at room temperature and then at 0.1 x SSC/0.1 x SDS at 65°C, and

determining the binding of the probe to a nucleic acid molecule in the sample to determine expression of the nucleic acid molecule, wherein the expression of the nucleic acid molecule is diagnostic for the presence of cancer in the subject.

2. The drawings filed 07/19/1999 are acceptable by USPTO Standards.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MINH-TAM DAVIS whose telephone number is 571-272-0830. The examiner can normally be reached on 9:30AM-4:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, YVONNE EYLER can be reached on 571-272-0871. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

MINH TAM DAVIS
February 24, 2004

SUSAN UNGAR, PH.D
PRIMARY EXAMINER

A handwritten signature in black ink, appearing to read 'Susan Ungar', is written over the printed name of the Primary Examiner.